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Gelbart

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(54) **APPARATUS AND METHOD FOR FORMING SELF-RETAINING SUTURES**

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B21F 25/00 (2006.01)
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USPC **29/7.1**; 606/146

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USPC 29/7.1, 7.2, 7.3; 606/146, 228, 215, 606/224, 216; 83/651
See application file for complete search history.

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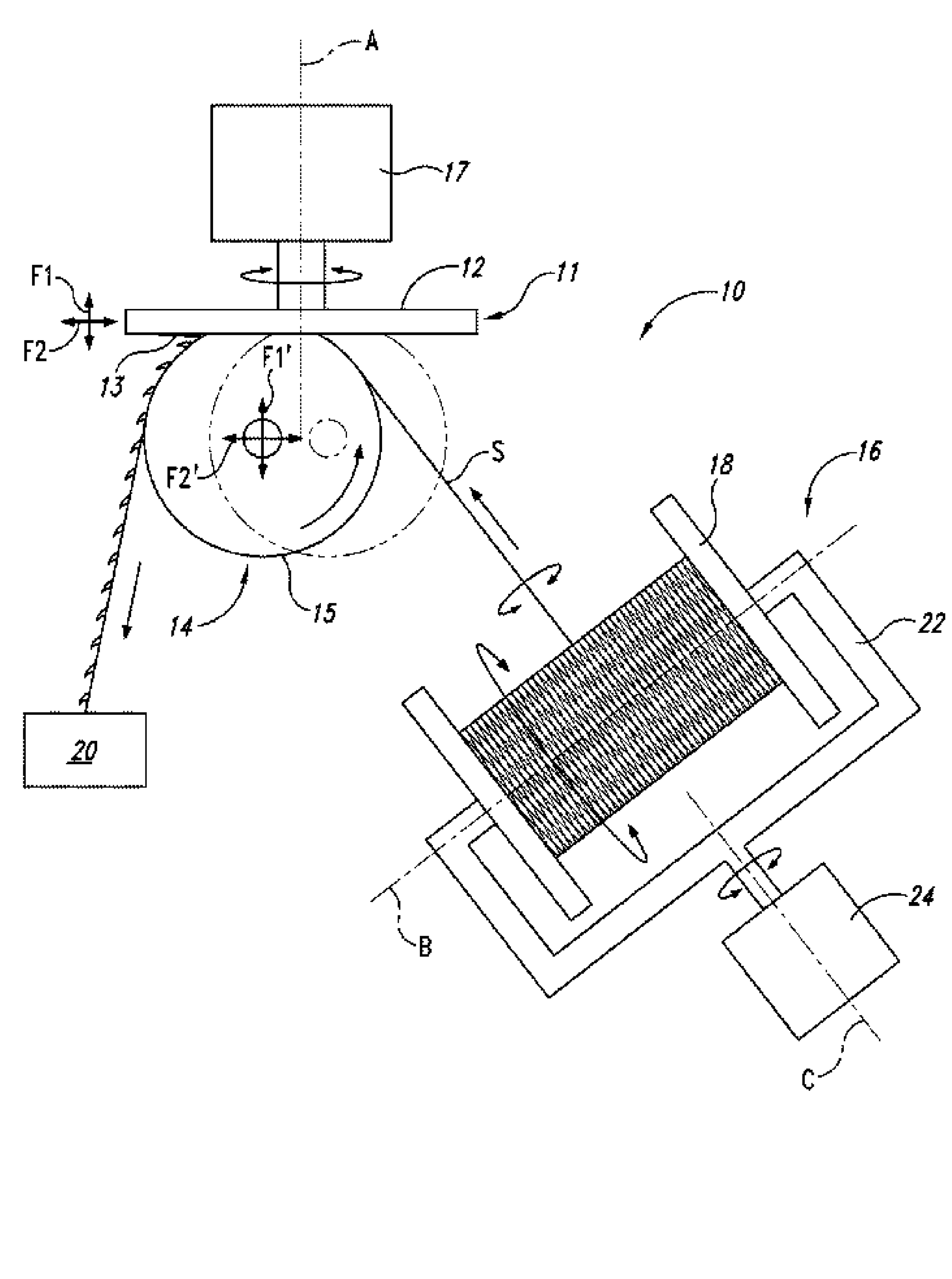
(57) **ABSTRACT**

An apparatus and method for forming retainers on a continuous strand such as, for example, of suture material and a suture produced by the same. The apparatus may include a retainer forming member configured to rotate about a first axis. The retainer forming member may include a cutter, the cutting edge of which may directed substantially inward toward, or outward away from, the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis. The apparatus may further include a support member arranged adjacent to the retainer forming member and configured to receive and support the continuous strand in the retainer forming zone. When the retainer forming member rotates about the first axis, the passing strand may be intermittently or continuously cut by the cutting edge of the cutter.

5 Claims, 12 Drawing Sheets



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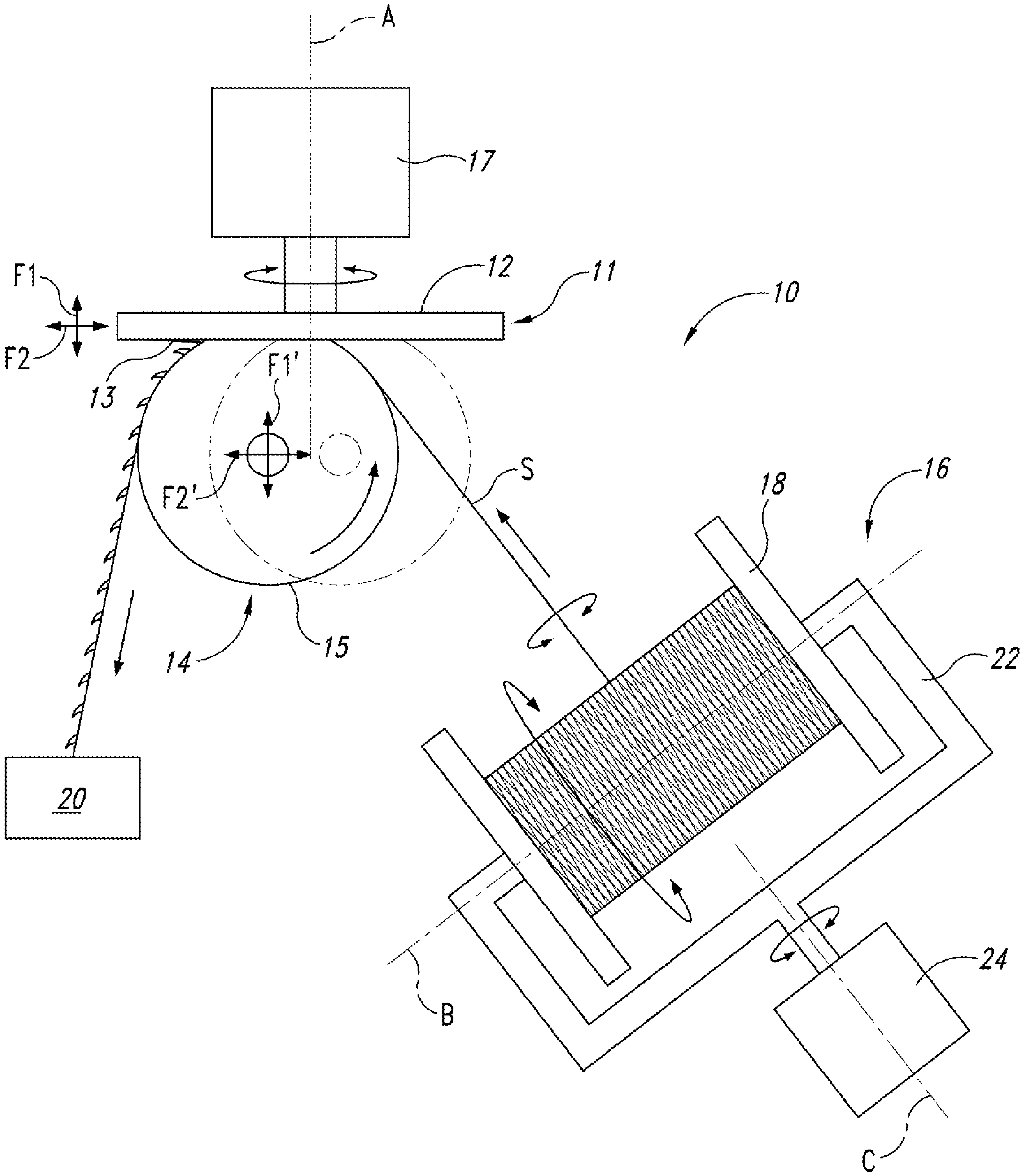

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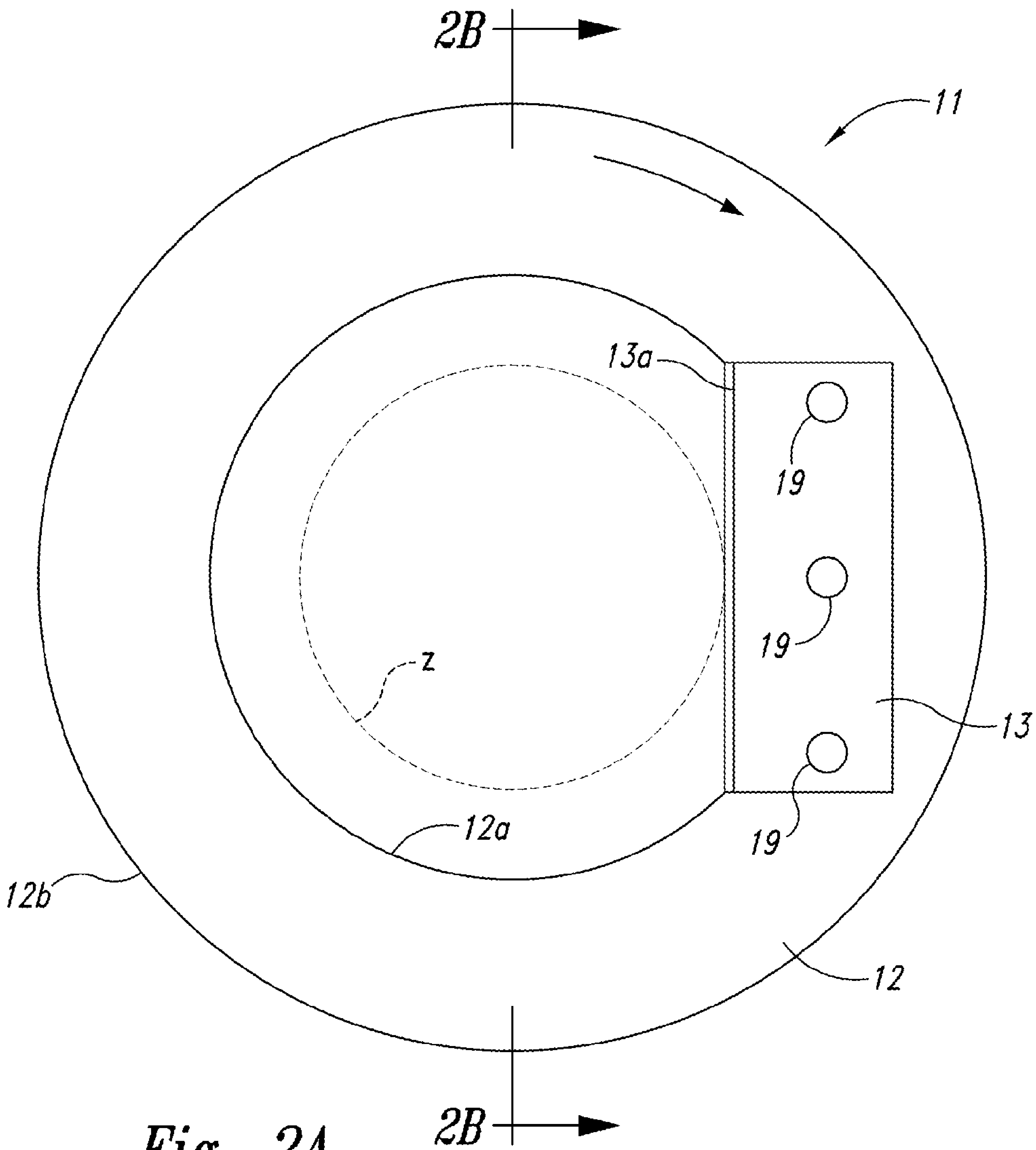

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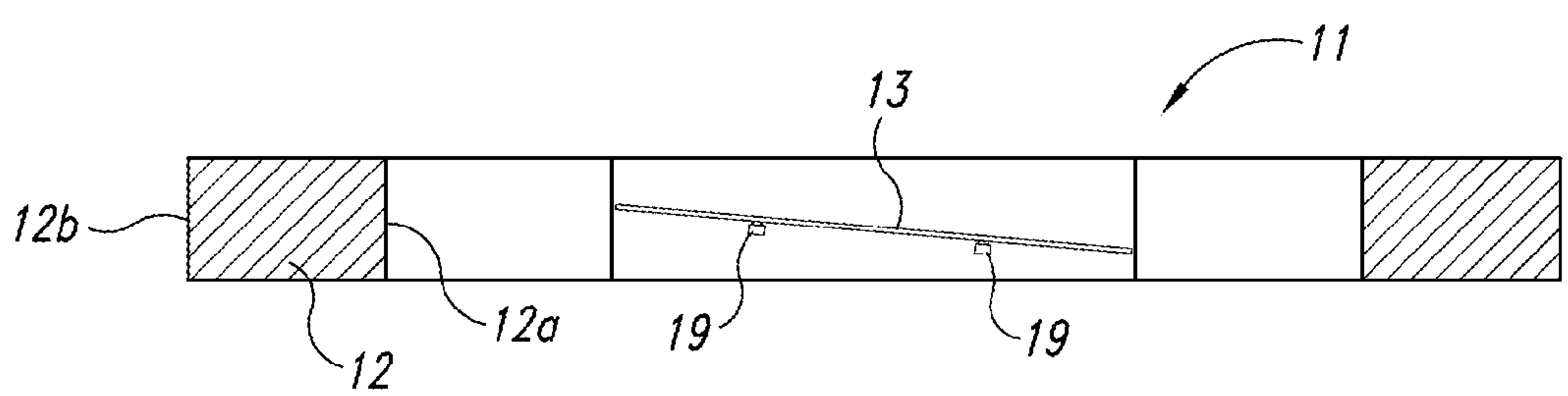

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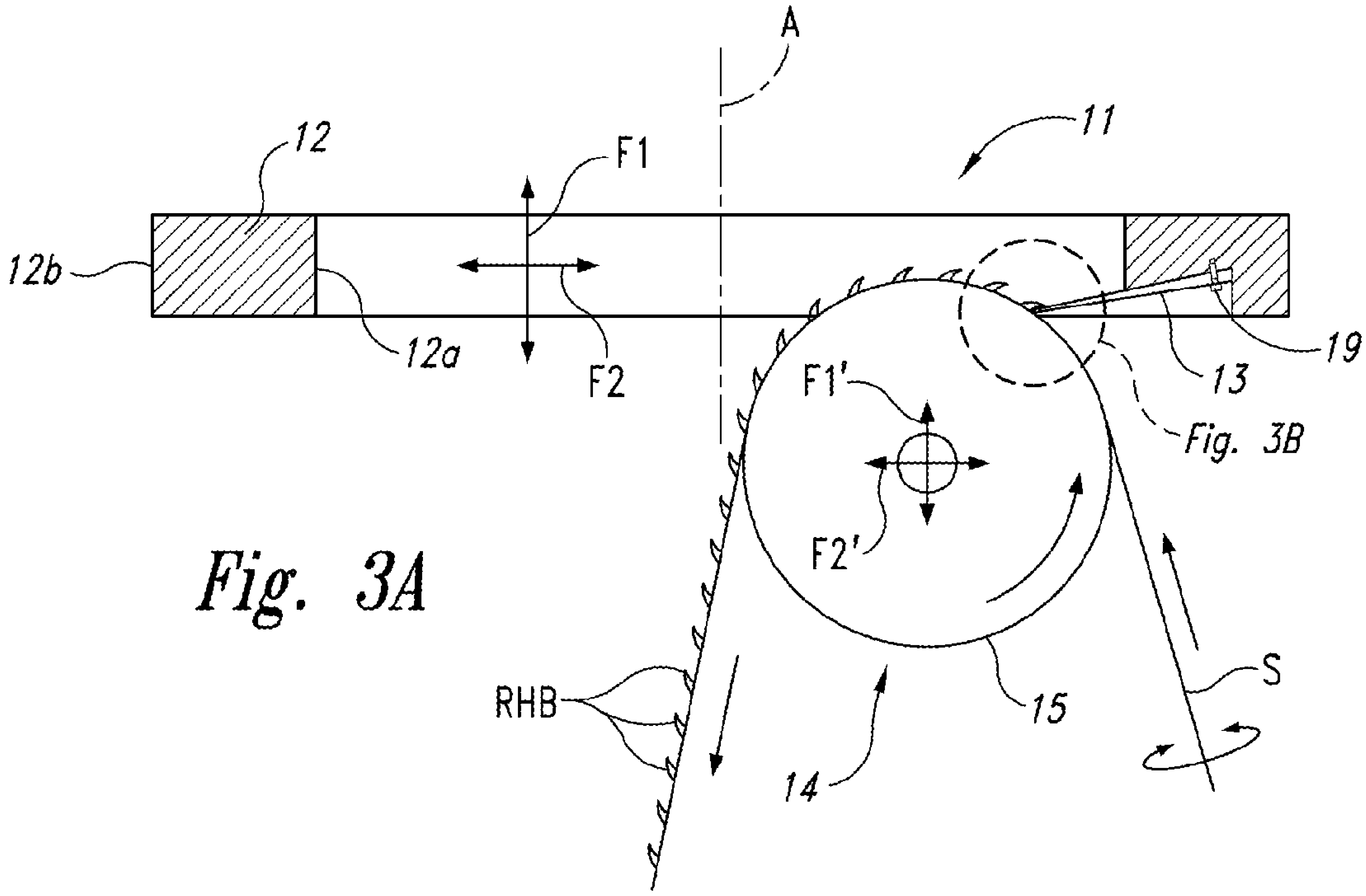
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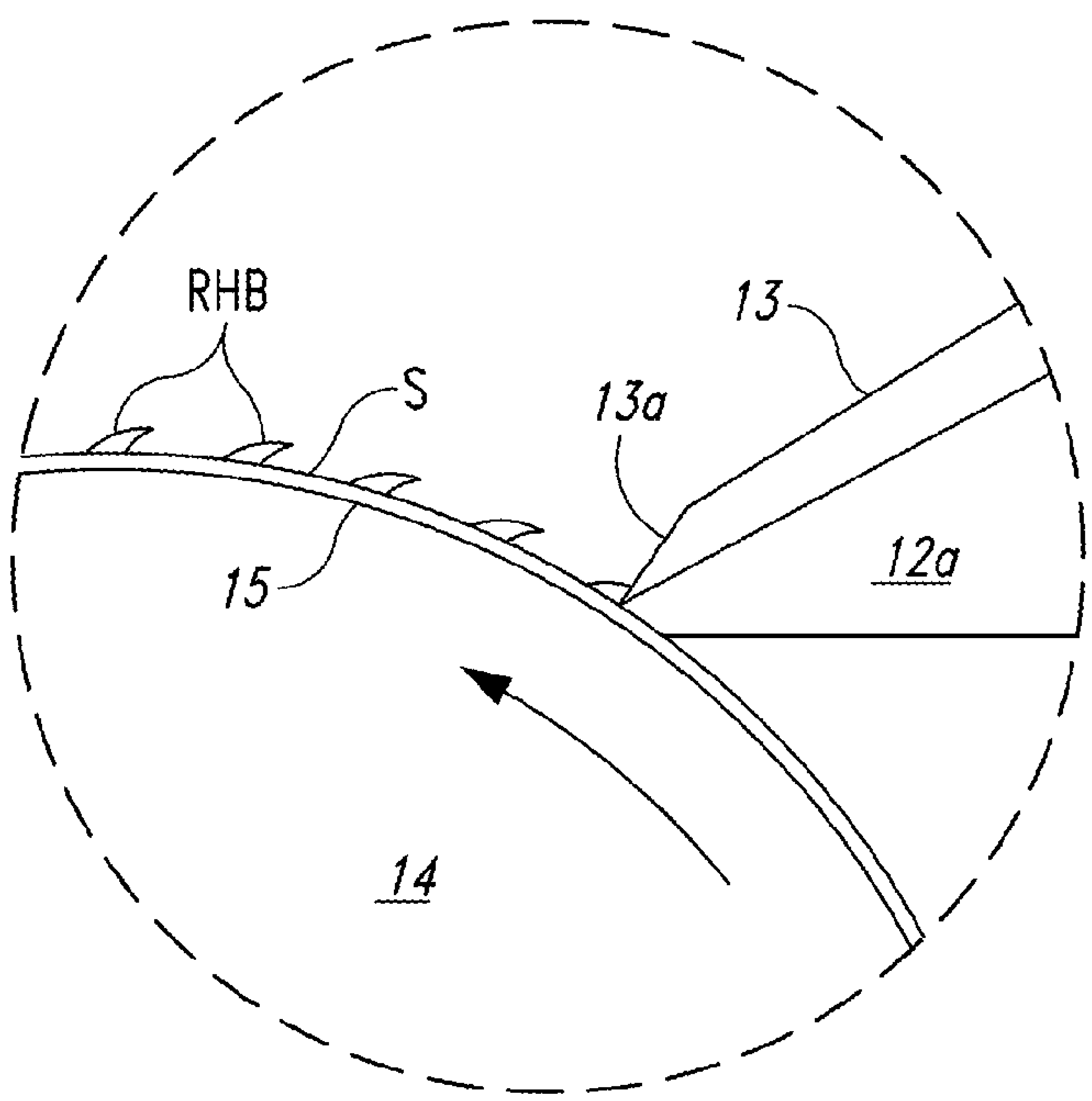
Fig. 3A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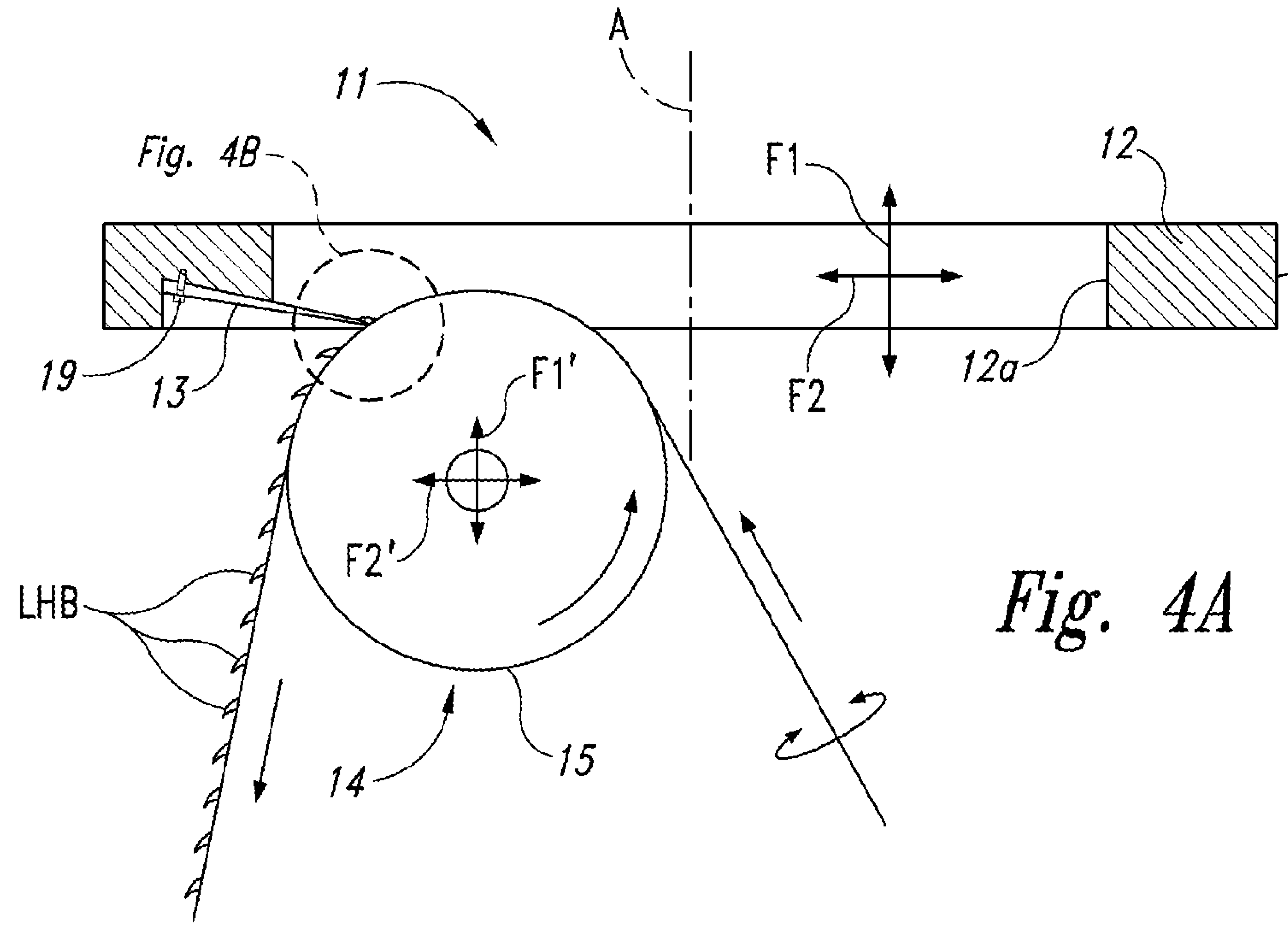
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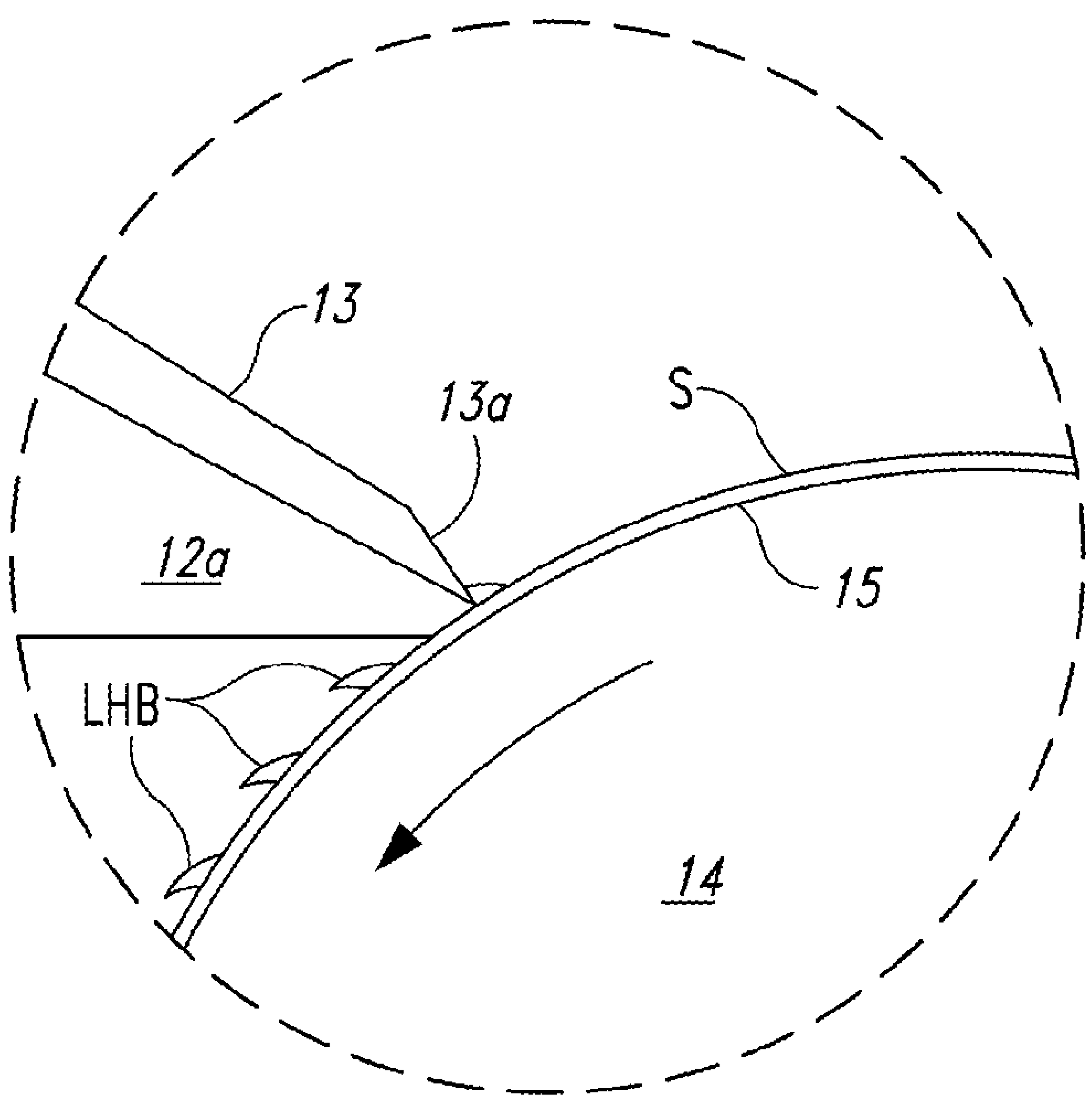
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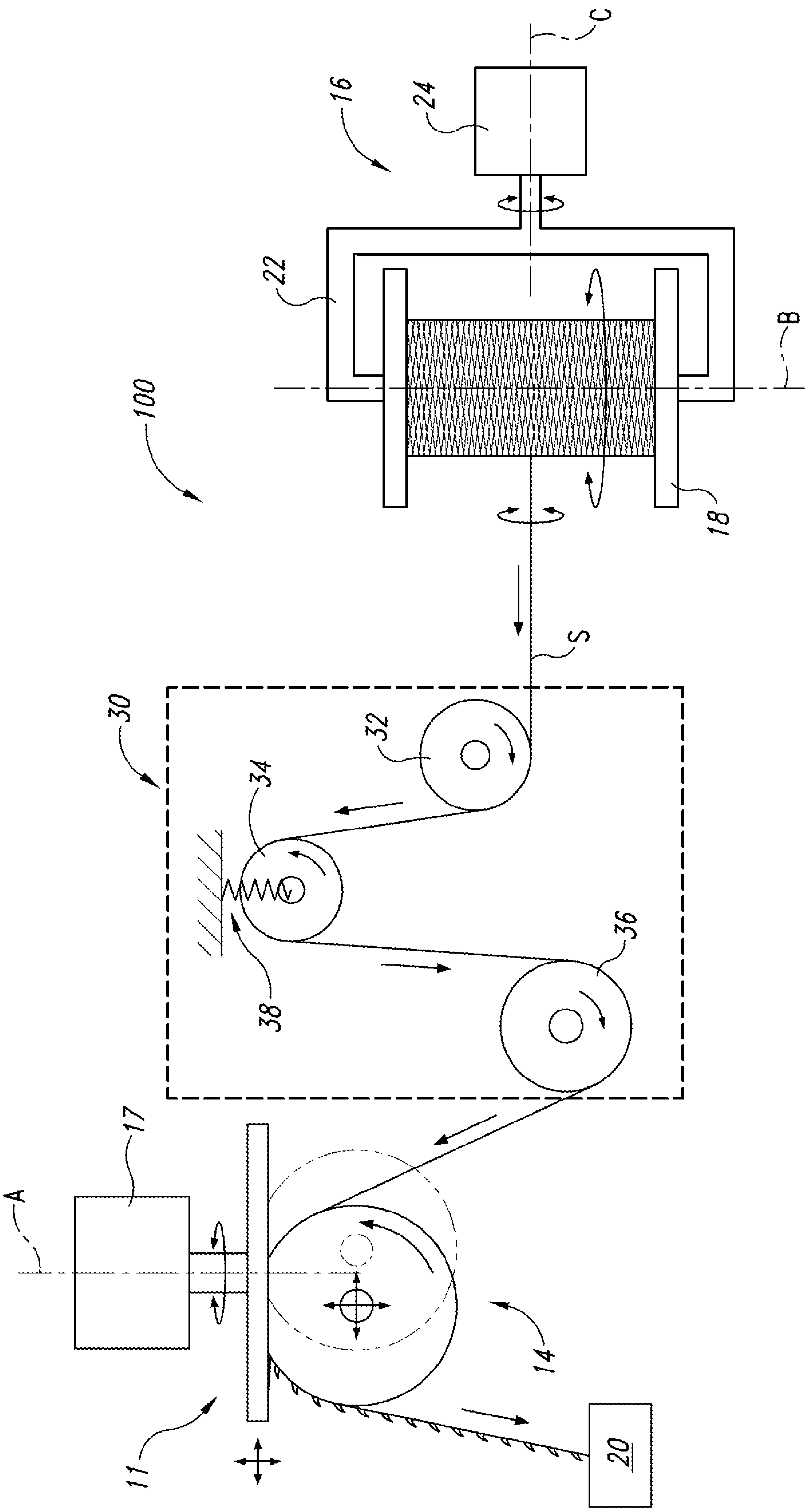

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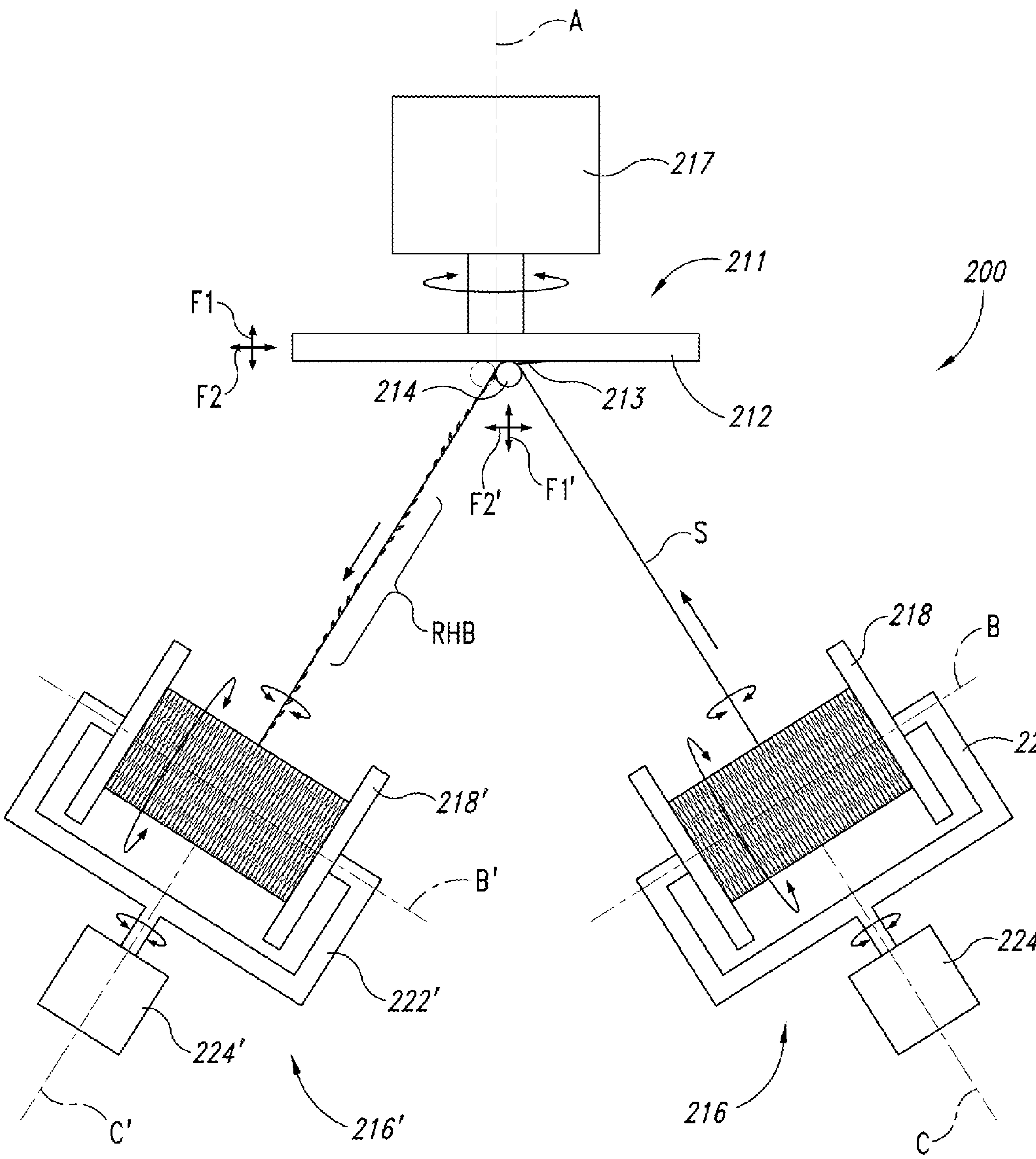
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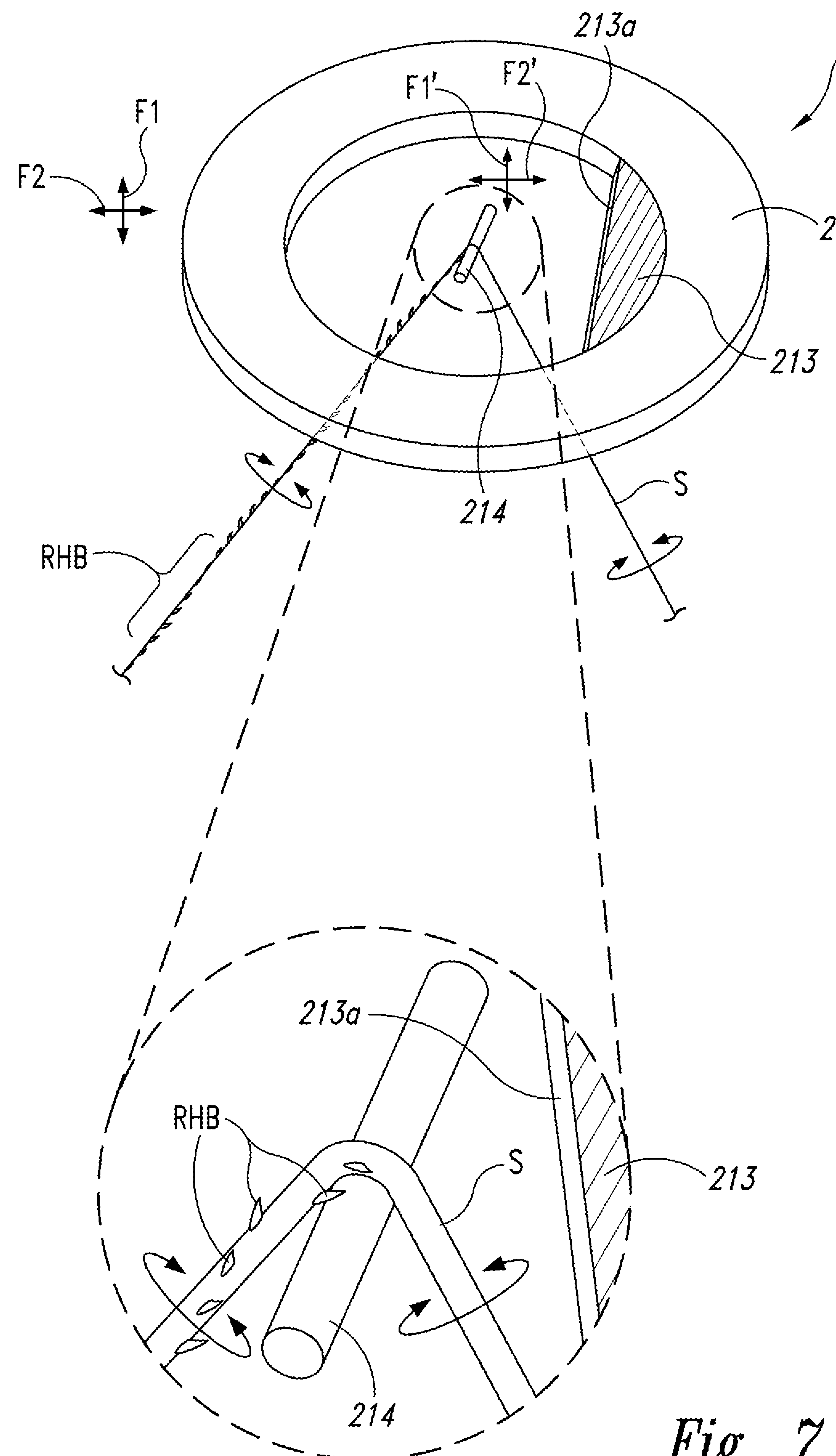
Fig. 6



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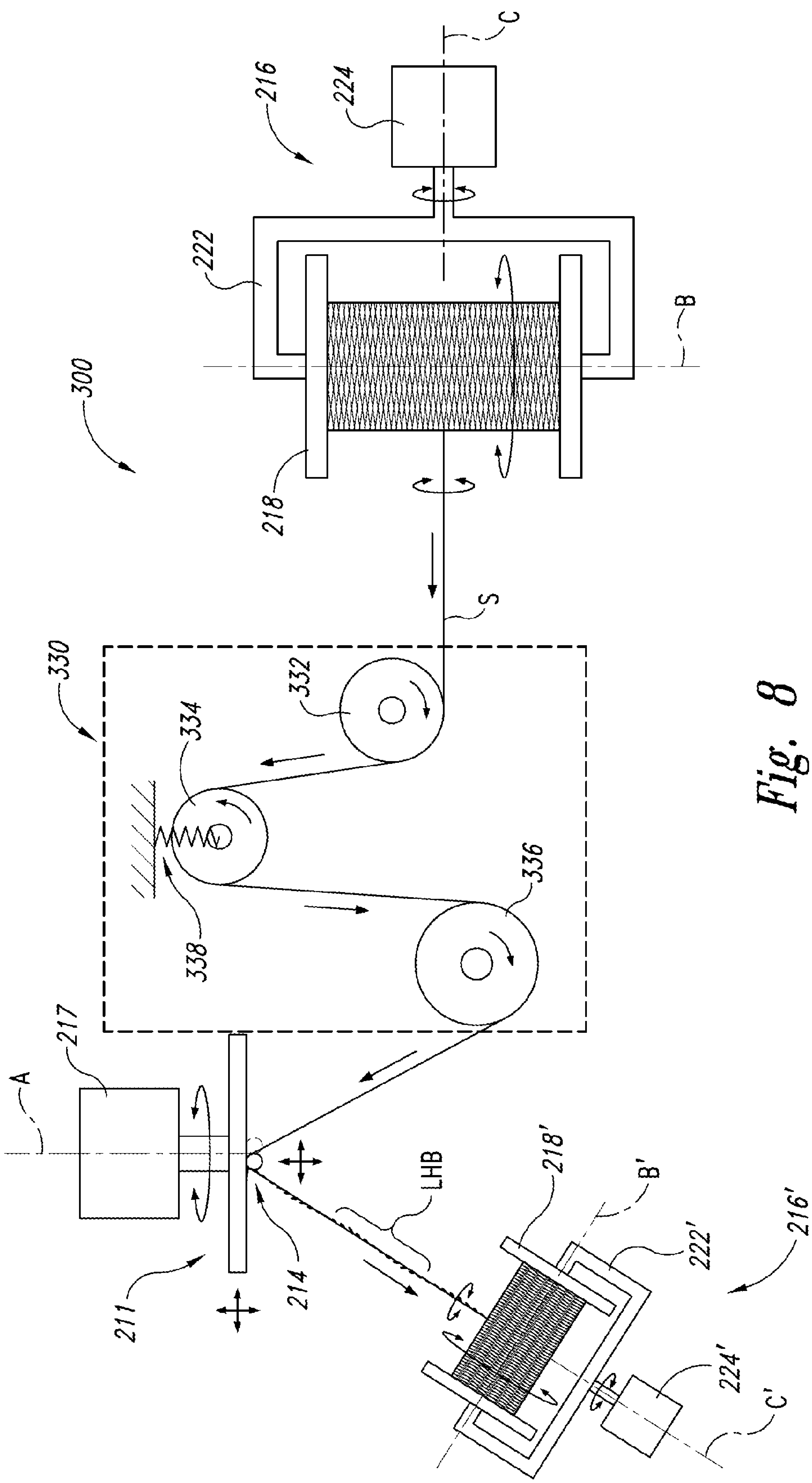
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Fig. 8

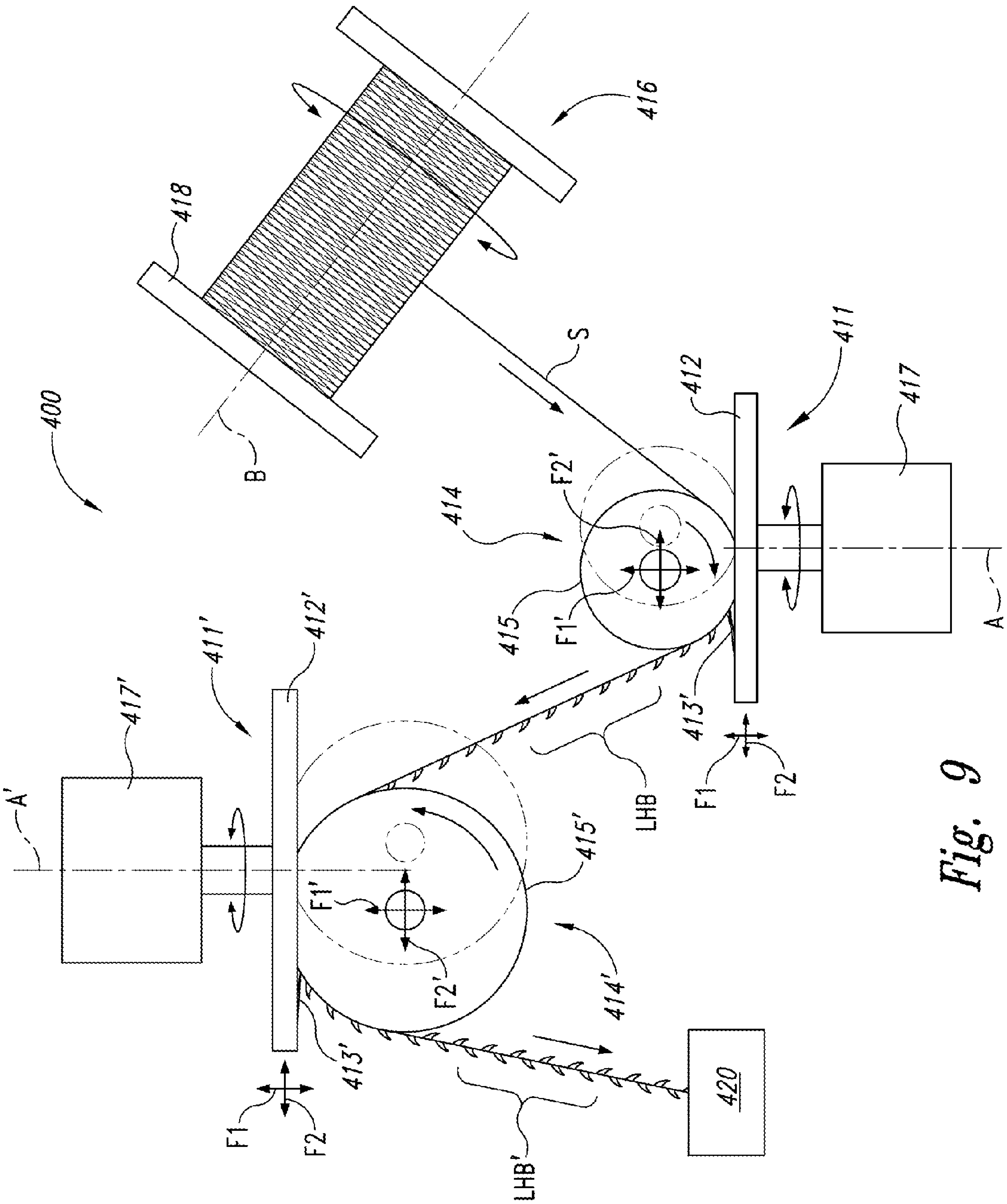
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Fig. 9

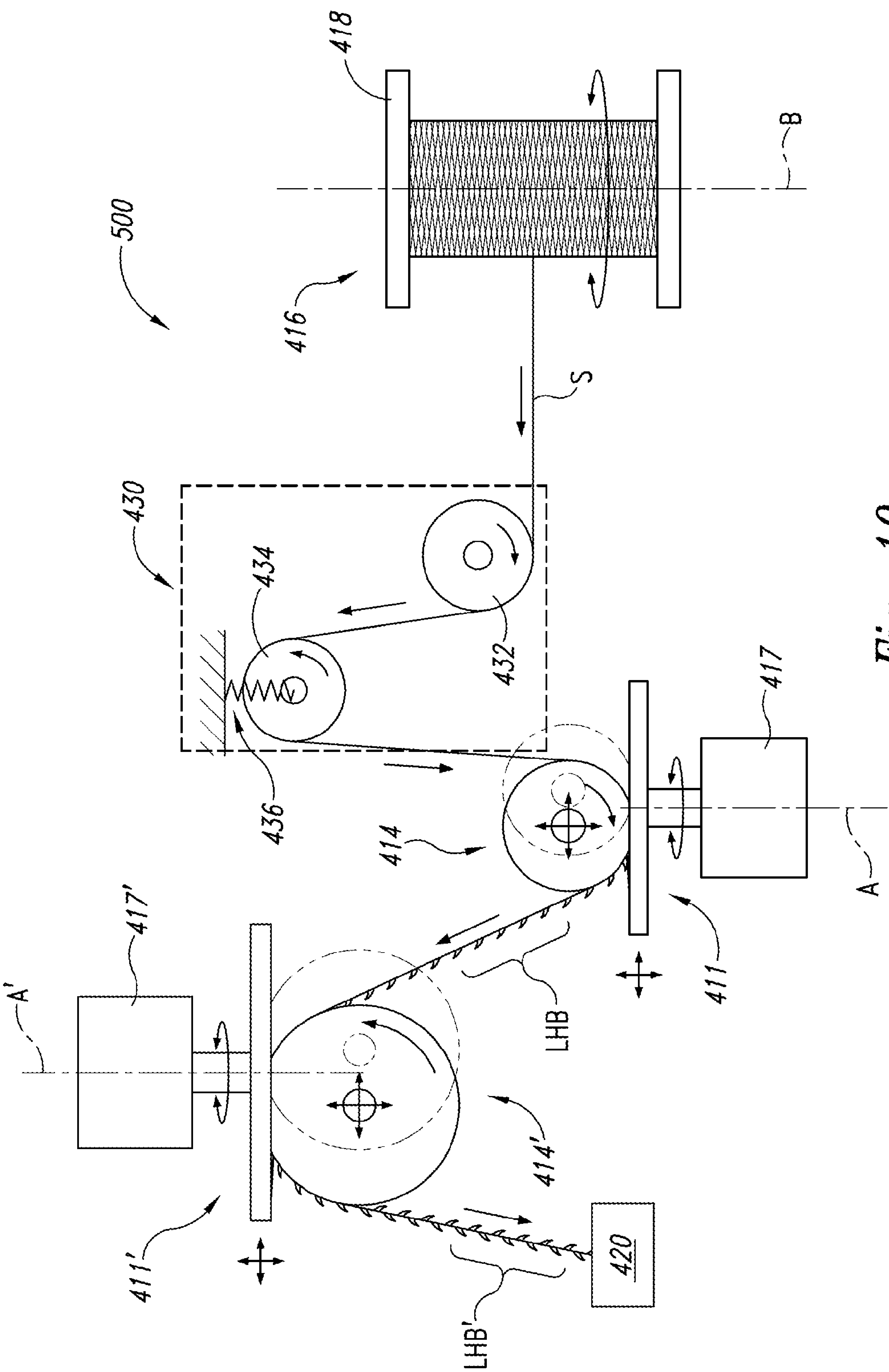
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Fig. 10

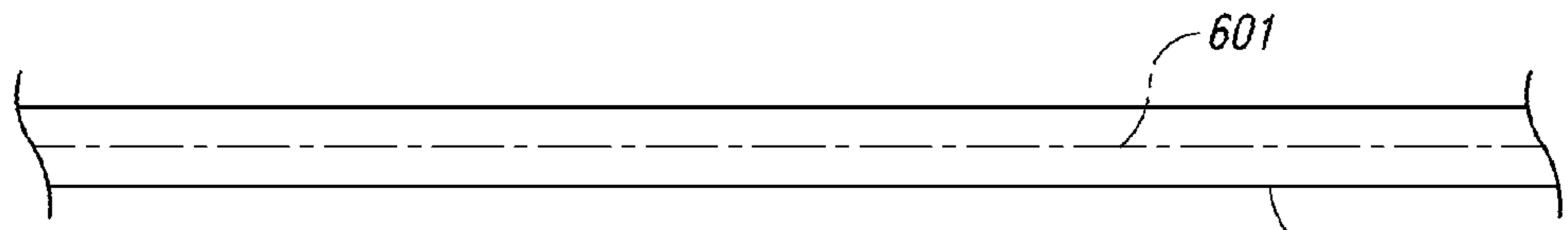


Fig. 11A

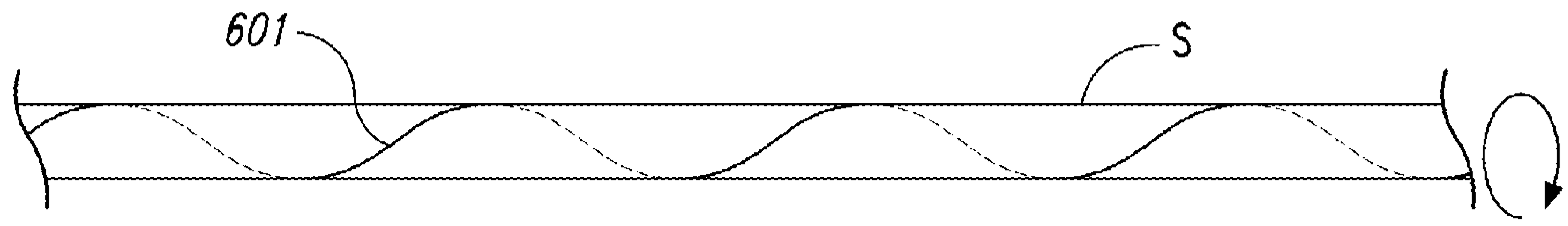
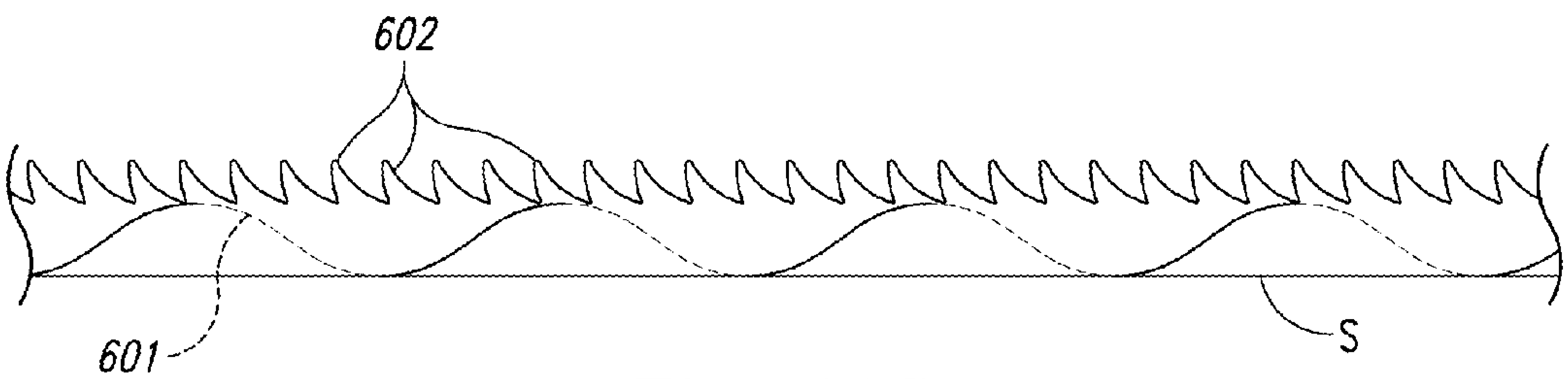


Fig. 11B



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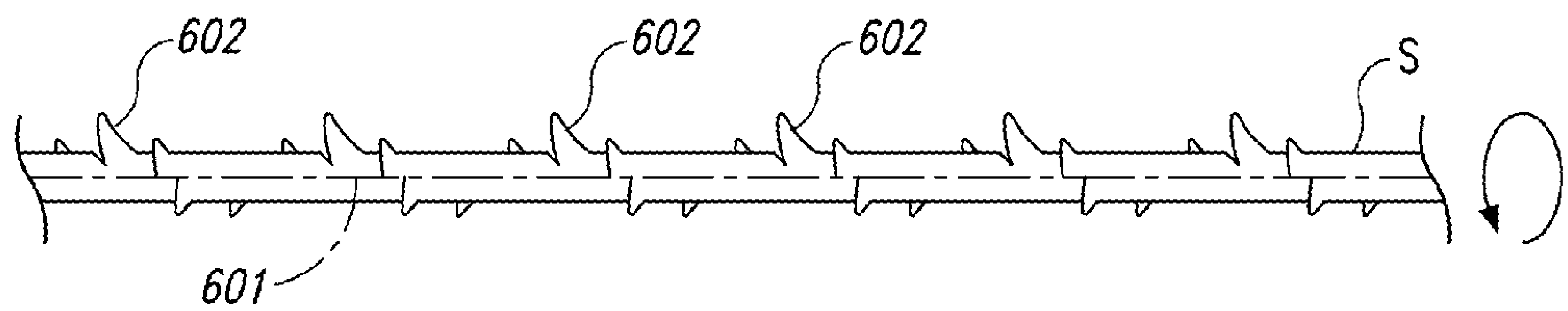

Fig. 11D

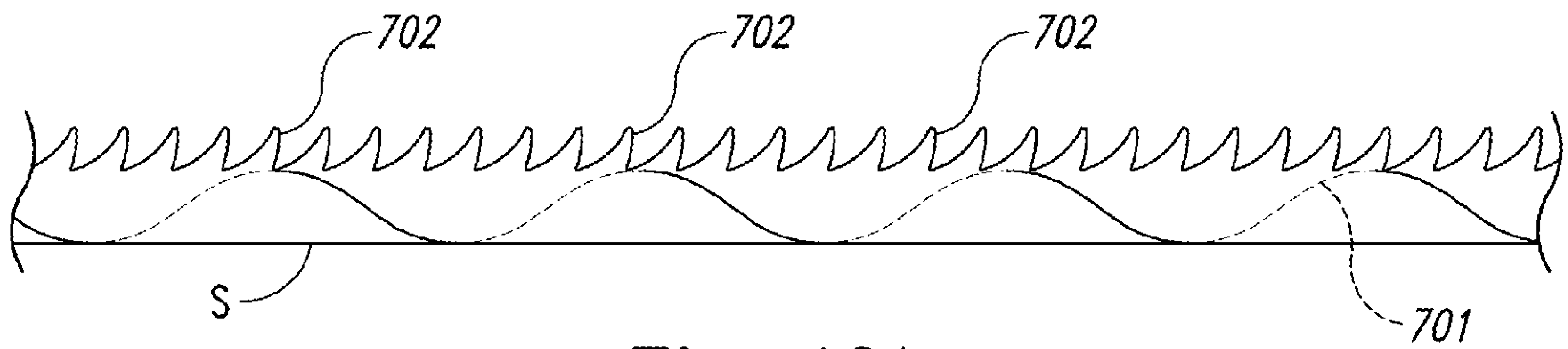

Fig. 12A

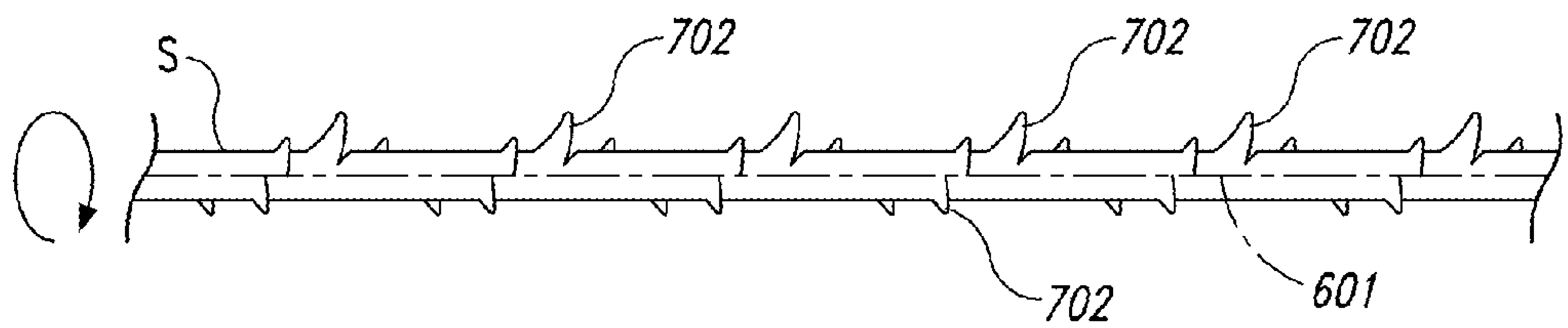

Fig. 12B

APPARATUS AND METHOD FOR FORMING SELF-RETAINING SUTURES

FIELD OF INVENTION

The present invention relates generally to an apparatus and method for forming retainers in a suture and, more particularly, to an apparatus including a rotary retainer forming member for forming retainers in a suture and method thereof.

DISCUSSION OF RELATED ART

A suture is an elongated body such as, for example, a strand, filament, wire, or thread, that typically includes a needle attached or formed on at least one end. In general, sutures are used in surgical procedures to close surgical and traumatic wounds, to close the skin in plastic surgery, to secure damaged or severed tendons, muscles or other internal tissues, and in microsurgery on nerves and blood vessels. Closure of wounds and/or holding tissues together facilitates healing and re-growth.

Complications associated with knots when using conventional sutures are well known. Such complications may include: suture breakage, knot slippage, suture extrusion, infection, dehiscence and excessive inflammatory response leading to ischemia and scarring. Attempts to overcome these deficiencies with knotless sutures in the past have gained little clinical success. More recently, the development of self-retaining sutures such as, for example, self-retaining sutures, has been reported.

A self-retaining suture may be a one-way needle-drawn knotless suture which allows passage of the suture in one direction through tissue, but not in the opposite direction. A self-retaining suture may generally include a pointed leading end such as, for example, a needle, and a plurality of tissue retainers on the exterior surface of the suture. The retainers may generally be formed to collectively extend in one direction along the length of the suture. While suturing tissue, these retainers may penetrate inside the tissue and lock in place so that no knots are needed to tie the suture.

Methods of using self-retaining sutures in surgical procedures are disclosed, for example, in U.S. Pat. No. 6,599,310, entitled "Suture Method", the disclosure of which is incorporated herein by reference. Self-retaining sutures may provide the ability to put tension in the tissue with the result of less slippage of the suture in the wound. Depending on the circumstances of a given tissue repair, a given configuration of retainers on the exterior of the suture may be more preferable than another.

Various methods and apparatuses for cutting retainers on the exterior of a suture have been proposed. For example, U.S. Pat. Nos. 7,225,512, 6,848,152, and 5,931,855, each of which is hereby incorporated herein by reference in its entirety, are related to self-retaining sutures and methods for making such sutures. In general, however, these apparatuses and methods may be directed to linearly reciprocating cutting devices and the like.

SUMMARY

The apparatus and method described herein may reliably achieve a high output efficiency of self-retaining suture material based on length per second or retainers per second while providing the ability to form countless retainer configurations on the suture with one apparatus requiring limited set-up and/or changeover.

In one exemplary embodiment, an apparatus for forming retainers on a continuous strand is provided. The continuous strand may be a suture material. The apparatus may include a retainer forming member configured to rotate about a first axis. The retainer forming member may include a blade. A cutting edge of the blade may be directed substantially inward toward the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis. The apparatus may further include a support member arranged adjacent to the retainer forming member and configured to receive and support the continuous strand in the retainer forming zone. When the retainer forming member rotates about the first axis the strand is intermittently or continuously cut by the cutting edge of the blade.

The retainer forming member and the support member may be moveable relative to one another to position the support member in the retainer forming zone so that the strand received and supported thereon can be cut by the blade as the retainer forming member rotates about the first axis. The support member may include a sheave configured to rotate about a second axis, such second axis being nonparallel to the first axis. Further, the second axis may be substantially perpendicular to the first axis. In addition, the retainer forming member may be movable along the first axis relative to the support member. As well, the retainer forming member may be movable along a third axis perpendicular to both the first and second axes between a first position and a second position, such that when the retainer forming member is in the first position the blade cuts retainers on the strand extending in a first direction and when the retainer forming member is in the second position the blade cuts retainers on the strand extending in a second direction opposite to the first direction. The retainer forming member may further be one of a plurality of retainer forming members disposed along a path of travel of the continuous strand, such that another retainer forming member of the plurality of retainer forming members is arranged at a different angle from the first retainer forming member about a periphery of the strand to cut the strand at a different point on the periphery of the strand.

The support member of this apparatus may be movable along the first axis relative to the retainer forming member. The support member may additionally be movable along a third axis perpendicular to both the first and second axes between a first position and a second position, such that when the support member is in the first position the blade of the retainer forming member cuts retainers on the strand extending in a first direction and when the support member is in the second position the blade of the retainer forming member cuts retainers on the strand extending in a second direction opposite to the first direction.

The apparatus may also include a feed mechanism configured to receive and support an input spool of the continuous strand such that the spool can rotate to unwind the strand from the spool, the feed mechanism being configured to rotate the spool so that the strand rotates about its own axis. In addition, the feed mechanism may be configured to twist the strand about its own axis.

The apparatus may also include a take-up mechanism configured to pull the strand from the input spool about a surface of the support member. Such take-up mechanism may be configured to receive and wind the continuous strand on an output spool after cutting. The take-up mechanism may also be configured to rotate the strand about its own axis concurrently with the feed mechanism so that the strand is not twisted between any two points along its length.

In another exemplary embodiment, a method for forming retainers on a continuous strand with the apparatus is provided. The method may include rotating the retainer forming member of the apparatus about the first axis, moving the continuous strand on the support member within the retainer forming zone, and intermittently or continuously cutting the strand with the cutting edge of the blade as the retainer forming member rotates to form retainers on the strand.

The strand may be moved by pulling the strand through the retainer forming zone about a surface of the support member with a take-up mechanism. The method may further include rotating or twisting the strand about its own axis. The continuous strand may be a suture material.

At least one of the retainer forming member or the support member may be moved relative to the other. The retainer forming member may also be moved along the first axis relative to the support member. Additionally or alternatively, the support member may be moved along the first axis relative to the retainer forming member.

The support member may include a sheave configured to rotate about a second axis which is nonparallel to the first axis. Thus the method may further include moving the retainer forming member along a third axis perpendicular to both the first and second axes to a first position, such that the cutting edge of the blade cuts retainers on the strand extending in a first direction. The method may also include moving the retainer forming member along the third axis to a second position, such that the cutting edge of the blade cuts retainers on the strand extending in a second direction opposite to the first direction.

The method may alternatively include moving the support member along a third axis perpendicular to both the first and second axes to a first position, such that the cutting edge of the blade cuts retainers on the strand extending in a first direction. This method may also include moving the support member along the third axis to a second position, such that the cutting edge of the blade cuts retainers on the strand extending in a second direction opposite to the first direction. In either case, the second axis may be substantially perpendicular to the first axis.

The support member may have a small surface area which receives and supports the strand so that the retainers formed on the strand do not contact the surface of the support member as the strand is rotated and advanced away from the retainer forming zone.

In yet another exemplary embodiment of the invention, a suture having a plurality of retainers formed on an outer periphery of a strand of suture material is provided. The suture may be formed by a method. The method may include the steps of: providing a retainer forming member configured to rotate about a first axis and comprising a blade, wherein a cutting edge of the blade is directed substantially inward toward the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis; providing a support member arranged adjacent to the retainer forming member and configured to receive and support the strand of suture material in the retainer forming zone; rotating the retainer forming member about the first axis; moving the strand of suture material on the support member within the retainer forming zone; and intermittently or continuously cutting the strand of suture material with the cutting edge of the blade as the retainer forming member rotates to form a plurality of retainers on the strand of suture material. The suture may formed from an absorbable or a non-absorbable material. The strand of suture material may further be cut into individual sutures having a predetermined length.

The plurality of retainers of the suture may project in a first direction, and may be formed by moving the retainer forming member to a first position in the retainer forming zone. The plurality of retainers may further project in a second direction opposite to the first direction, and the retainers projecting in the second direction may formed by moving the retainer forming member to a second position in the retainer forming zone.

Alternatively, the plurality of retainers projecting in the first direction may formed by moving the support member to a first position in the retainer forming zone. The plurality of retainers may further project in a second direction opposite to the first direction, and retainers projecting in the second direction may be formed by moving the support member to a second position in the retainer forming zone.

The plurality of retainers cut on the outer periphery of the strand of suture material may be arranged helically along the length of the strand, and may be formed by rotating or twisting the strand about its own axis during cutting.

In yet another embodiment, an apparatus for forming retainers on a continuous strand is provided. The apparatus may include means for intermittently or continuously cutting a continuous strand; means for rotating the cutting means about a first axis to define a retainer forming zone; and means for supporting and moving the continuous strand in the retainer forming zone as the strand is cut by the cutting means. The apparatus may further include means for rotating the strand about its own axis and/or means for means for twisting the strand about its own axis.

The apparatus may further include means for moving at least one of the cutting means or the supporting and moving means relative to the other. The moving means may be configured for moving the cutting means to a first position, such that the cutting means cuts retainers on the strand extending in a first direction. The moving means may also be configured for moving the cutting means to a second position, such that cutting means cuts retainers on the strand extending in a second direction opposite to the first direction.

The moving means may be configured for moving the supporting and moving means to a first position, such that the cutting means cuts retainers on the strand extending in a first direction. As well, the moving means may be configured for moving the supporting and moving means to a second position, such that the cutting means cuts retainers on the strand extending in a second direction opposite to the first direction.

In still another embodiment, a method of forming retainers in a surgical suture is provided. The method may include unidirectionally rotating a blade about an axis to form retainers in a continuous strand of suture material, wherein the blade moves relative to the continuous strand in at least two directions while cutting each retainer. A first of the at least two directions may be approximately perpendicular to a longitudinal axis of the continuous strand and a second of the at least two directions may have a component parallel to the longitudinal axis of the strand. Further, there may be an optional third direction in which the blade moves relative to the continuous strand, the third direction being approximately perpendicular to each of the first and second directions. Further, a cutting edge of the blade substantially may point toward the axis about which the blade rotates. Alternatively, a cutting edge of the blade may substantially point away from the axis about which the blade rotates.

In yet another embodiment, a suture comprising a plurality of retainers formed on an outer periphery of a strand of suture material is provided. The suture may be formed by an apparatus comprising a retainer forming member configured to rotate about a first axis. The retainer forming member may include a blade having a cutting edge directed substantially inward toward the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis.

The apparatus may further include a support member disposed adjacent the retainer forming member and configured to receive and support the strand of suture material in the retainer forming zone. The strand of suture material may be moved on the support member within the retainer forming zone and the strand of suture material may be intermittently or continuously cut by the cutting edge of the blade as the retainer forming member rotates, thereby forming a plurality of retainers on the strand of suture material.

In still another embodiment, an apparatus for cutting retainers on a continuous strand is provided. The apparatus may include a blade operable to unidirectionally and continuously rotate about an axis. A cutting edge of the blade may define a retainer forming zone when the blade rotates about the axis. The apparatus may include a support member configured to support the strand in the retainer forming zone. When the blade rotates about the axis and the support member supports the passing strand in the retainer forming zone, the blade may intermittently or continuously cut retainers on the passing strand.

In still another embodiment, a surgical suture comprising at least one retainer formed on an outer periphery of a strand of suture material is provided. The surgical suture may be formed by a method including unidirectionally rotating a blade about an axis to form at least one retainer on the outer periphery of the strand of suture material. The blade may move relative to the continuous strand in at least two directions while cutting the at least one retainer.

The details of one or more aspects or embodiments are set forth in the description below. Other features, objects and advantages will be apparent from the description, the drawings and the claims. In addition, the disclosures of all patents and patent applications referenced herein are incorporated by reference in their entirety.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features and advantages of the invention will be apparent from the following, more particular description of the exemplary embodiments of the invention, as illustrated in the accompanying drawings.

Several exemplary embodiments of the invention will be described with respect to the following drawings, in which like reference numerals represent like features throughout the figures, and in which:

FIG. **1** is a schematic view of an apparatus for forming retainers in a continuous strand according to an embodiment of the invention;

FIG. **2**A is a schematic bottom view of the retainer forming member according to the embodiment shown in FIG. **1**;

FIG. **2**B is a cross-sectional side view of the retainer forming member of FIG. **2**A taken through line **2**B-**2**B;

FIG. **3**A is a cross-sectional side view of the retainer forming member shown in FIG. **1** with the support member shown in a first operational position within the retainer forming zone;

FIG. **3**B is a detailed view of the retainer forming member and the support member according to the embodiment shown in FIG. **3**A;

FIG. **4**A is a cross-sectional side view of the retainer forming member shown in FIG. **1** with the support member shown in a second operational position within the retainer forming zone;

FIG. **4**B is a detailed view of the retainer forming member and the support member according to the embodiment shown in FIG. **4**A;

FIG. **5** is a schematic view of the apparatus for forming retainers in a continuous strand according to the embodiment shown in FIG. **1** including a strand tension maintenance mechanism;

FIG. **6** is a schematic view of the apparatus for forming retainers in a continuous strand according to yet another embodiment of the invention;

FIG. **7** is an illustrative perspective view of the apparatus in FIG. **6**;

FIG. **8** is a schematic view of the apparatus for forming retainers in a continuous strand according to the embodiment shown in FIG. **6** including a strand tension maintenance mechanism;

FIG. **9** is a schematic view of the apparatus for forming retainers in a continuous strand according to still another embodiment of the invention;

FIG. **10** is a schematic view of the apparatus for forming retainers in a continuous strand according to the embodiment shown in FIG. **9** including a strand tension maintenance mechanism;

FIG. **11**A is a schematic depiction of the continuous strand or suture prior to being twisted, rotated or cut;

FIG. **11**B is a schematic depiction of the continuous strand or suture after being twisted but prior to being cut;

FIG. **11**C is a schematic depiction of the continuous strand or suture after being twisted and cut to have retainers facing in a first direction;

FIG. **11**D is a schematic depiction of the continuous strand or suture of FIG. **11**C after being untwisted from a twisted state;

FIG. **12**A is a schematic depiction of the continuous strand or suture after being twisted and cut to have retainers facing in a second direction; and

FIG. **12**B is a schematic depiction of the continuous strand or suture of FIG. **12**A after being untwisted from a twisted state.

DETAILED DESCRIPTION

In describing the various exemplary embodiments illustrated in the drawings, specific terminology is employed for the sake of clarity. However, the invention is not intended to be limited to the specific terminology so selected. It is to be understood that each specific element includes all technical equivalents that operate in a similar manner to accomplish a similar purpose.

In the following description of certain embodiments of the invention, directional words such as "top," "bottom," "upwardly," and "downwardly" are employed by way of description and not limitation with respect to the orientation of the apparatus and its various components as illustrated in the drawings. Similarly, directional words such as "axial" and "radial" are also employed by way of description and not limitation.

EXEMPLARY DEFINITIONS

The term "tissue retainer" (and variations thereof such as, for example, "retainer" or "barb") as used herein, may refer to a point or pointed part projecting from a strand such as, for example, a suture element having a retainer body projecting from the suture body and a retainer end adapted to penetrate tissue. Each retainer is adapted to resist movement of the suture in a direction other than the direction in which the suture is deployed into the tissue by the surgeon, by being oriented to substantially face the deployment direction (i.e. they lie flat when pulled in the deployment direction; and open or "fan out" when pulled in a direction contrary to the deployment direction). As the tissue-penetrating end of each retainer faces away from the deployment direction when moving through tissue during deployment, the tissue retainers should not catch or grab tissue during this phase. Once the self-retaining suture has been deployed, a force exerted in another direction (often substantially opposite to the deployment direction) causes the retainers to be displaced from their deployment positions (i.e. resting substantially along the suture body), forces the retainer ends to open (or "fan out") from the suture body in a manner that catches and penetrates into the surrounding tissue, and results in tissue being caught between the retainer and the suture body; thereby "anchoring" or affixing the self retaining suture in place.

The term "retainer configurations" (and variations thereof such as, for example, but not limited to "barb configurations") may refer to configurations of tissue retainers and can include features such as size, shape, surface characteristics, and so forth.

The term "blade" (and variations thereof), as used herein, may refer to the cutting part of a sharpened tool or member.

The term "continuous" (and variations thereof), as used herein, may mean substantially uninterrupted in time, sequence, substance, or extent.

The term "sheave" (and variations thereof), as used herein, may refer to a wheel or disk with a grooved rim. A non-limiting example of a sheave may include a pulley.

The term "spool" (and variations thereof), as used herein, may refer to any member or device on which something is wound.

The term "strand" (and variations thereof), as used herein, may refer to a thin elongated cord, thread, or filament of natural or synthetic material.

The term "suture" (and variations thereof), as used herein, may refer to an elongated body such as, for example, but not limited to, a strand, filament, wire, thread, or other material to be used surgically to close a wound or join tissues.

The term "transition segment" (and variations thereof such as, for example, but not limited to "transition portion") may refer to a retainer-free (barb-free) portion of a suture such as, for example, the portion on a bi-directional suture located between a first set of retainers oriented in one direction and a second set of retainers oriented in another direction.

The term "suture thread" may refer to the filamentary body component of a suture, and, for sutures requiring needle deployment, does not include the suture needle. The suture thread may be monofilamentary, or, multifilamentary.

The term "monofilament suture" may refer to a suture comprising a monofilamentary suture thread.

The term "braided suture" may refer to a suture comprising a multifilamentary suture thread. The filaments in such suture threads are typically braided, twisted, or woven together.

The term "self-retaining suture" (and variations thereof such as, for example, but not limited to, "barbed suture") may refer to a suture that does not require a knot or a suture anchor at its end in order to maintain its position into which it is deployed during a surgical procedure. "Self-retaining suture" may refer to a suture with one or more retainers located along the suture. The retainers may be of sufficient size and appropriate geometry for fastening to, or gripping, tissue through which the self-retaining suture is inserted and achieving closure of an incision or wound (or repositioning tissue) with superior attachment or without the need for tying knots. Retainers may be configured to have tissue insertion points (such as, for example, barbs), tissue insertion edges (such as conical or frusto-conical retainers), and so forth. These sutures may be monofilament sutures or braided sutures, and are positioned in tissue in two stages, namely deployment and affixation, and include at least one tissue retainer.

The term "retainer forming member" as used herein may include cutters such as blades, grinding wheels, cutting discs, and lasers (both cutting and vaporising lasers).

The term "one-way self-retaining suture" (and variations thereof such as, for example, but not limited to "one-directional suture," "one-directional self-retaining suture," "one-way suture," "uni-directional self-retaining suture," or "uni-directional suture") may refer to a suture having retainers (e.g., barbs) on its exterior surface and facing towards one end of the suture. Such arrangement of retainers on the suture may allow the suture to be drawn in only one direction through tissue, but not in the opposite direction.

The term "two-way self-retaining suture" (and variations thereof such as, for example, but not limited to "two-way suture," "two-directional self-retaining suture," "two-directional suture," "bi-directional self-retaining suture," or "bi-directional suture") may refer to a suture that has retainers (e.g., barbs) facing toward one end of the suture over a portion of the suture length and retainers (e.g., barbs) facing the opposite direction toward the other end of the suture over another portion of the suture length. This arrangement may allow the retainers to move in the same direction as each respective suture end is inserted into host tissue. A bi-directional suture may typically be armed with a needle at each end of the suture thread. Many bi-directional sutures may have a transitional segment located between the two retainer orientations.

The term "absorbable" (and variations thereof such as, for example, but not limited to, "degradable" or "biodegradable" or "bioabsorbable") may refer to materials for which an erosion or degradation process is at least partially mediated by, or performed in, a biological system. An absorbable suture may refer to a suture which, after introduction into a tissue is broken down and absorbed by the body. Typically, the degradation process is at least partially mediated by, or performed in, a biological system. "Degradation" refers to a chain scission process by which a polymer chain is cleaved into oligomers and monomers. Chain scission may occur through various mechanisms, including, for example, by chemical reaction (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination or these) or by a thermal or photolytic process. Polymer degradation may be characterized, for example, using gel permeation chromatography (GPC), which monitors the polymer molecular mass changes during erosion and breakdown. Degradable suture material may include polymers such as polyglycolic acid, copolymers of glycolide and lactide, copolymers of trimethylene carbonate and glycolide with diethylene glycol (e.g., MAXON™, Tyco Healthcare Group), terpolymer composed of glycolide, trimethylene carbonate, and dioxanone (e.g., BIOSYN™ [glycolide (60%), trimethylene carbonate (26%), and dioxanone (14%)], Tyco Healthcare Group), copolymers of glycolide, caprolactone, trimethylene carbonate, and lactide (e.g., CAPROSYN™, Tyco Healthcare Group). These sutures can be in either a braided multifilament form or a monofilament form. The polymers used in the present invention can be linear polymers, branched polymers or multi-axial polymers. Examples of multi-axial polymers used in sutures are described in U.S. Patent Application Publication Nos. 20020161168, 20040024169, and 20040116620. Sutures made from degradable suture material lose tensile strength as the material degrades.

The term "non-absorbable" (and variations thereof such as, for example, but not limited to, "non-degradable" or "non-biodegradable" or "non-bioabsorbable") may refer to material for a suture that is not degraded by chain scission such as chemical reaction processes (e.g., hydrolysis, oxidation/reduction, enzymatic mechanisms or a combination or these) or by a thermal or photolytic process. Non-degradable suture material includes polyamide (also known as nylon, such as nylon 6 and nylon 6.6), polyester (e.g., polyethylene terephthalate), polytetrafluoroethylene (e.g., expanded polytetrafluoroethylene), polyether-ester such as polybutester (block copolymer of butylene terephthalate and polytetra methylene ether glycol), polyurethane, metal alloys, metal (e.g., stainless steel wire), polypropylene, polyethelene, silk, and cotton. Sutures made of non-degradable suture material are suitable for applications in which the suture is meant to remain permanently or is meant to be physically removed from the body.

The term "suture diameter" may refer to the diameter of the body of the suture. It is to be understood that a variety of suture lengths may be used with the sutures described herein and that while the term "diameter" is often associated with a circular periphery, it is to be understood herein to indicate a cross-sectional dimension associated with a periphery of any shape. Suture sizing is typically based upon diameter. United States Pharmacopeia ("USP") designation of suture size runs from 0 to 7 in the larger range and 1-0 to 11-0 in the smaller range; in the smaller range, the higher the value preceding the hyphenated zero, the smaller the suture diameter. The actual diameter of a suture will depend on the suture material, so that, by way of example, a suture of size 5-0 and made of collagen will have a diameter of 0.15 mm, while sutures having the same USP size designation but made of a synthetic absorbable material or a non-absorbable material will each have a diameter of 0.1 mm. The selection of suture size for a particular purpose depends upon factors such as the nature of the tissue to be sutured and the importance of cosmetic concerns; while smaller sutures may be more easily manipulated through tight surgical sites and are associated with less scarring, the tensile strength of a suture manufactured from a given material tends to decrease with decreasing size. It is to be understood that the sutures and methods of manufacturing sutures disclosed herein are suited to a variety of diameters, including without limitation 7, 6, 5, 4, 3, 2, 1, 0, 1-0, 2-0, 3-0, 4-0, 5-0, 6-0, 7-0, 8-0, 9-0, 10-0 and 11-0.

The term "suture deployment end" may refer to an end of the suture to be deployed into tissue; one or both ends of the suture may be suture deployment ends. The suture deployment end may be attached to deployment means such as a suture needle, or may be sufficiently sharp and rigid to penetrate tissue on its own.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

FIG. **1** is a schematic view of an apparatus for forming retainers in a continuous strand according to an exemplary embodiment of the invention. The apparatus **10** may include a retainer forming member **11** and a support member **14** arranged adjacent to one another. The retainer forming member **11** may be arranged to be rotatably driven about an axis A by a first rotary drive device **17** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor) and may include a main body **12** and a blade **13** attached to the main body **12**. The blade **13** may have a cutting edge directed substantially inward toward the axis A. A feed mechanism **16** may be arranged to support an input spool **18** which supplies a continuous strand of material S to the support member **14** such that the retainer forming member **11** can form retainers on the strand S. A take-up mechanism **20** may be arranged to pull the continuous strand S from the input spool **18** about an outer surface of the support member **14**.

In the embodiment depicted in FIG. **1**, the continuous strand S is shown wound about the input spool **18**. The input spool **18** may be supported by a frame **22** such that the input spool **18** is freely rotatable about an axis B to allow the strand S to be unwound therefrom. The frame **22** may also be arranged to be rotatably driven about another axis C by a second rotary drive device **24** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor). In FIG. **1**, axis C is shown as being perpendicular to the axis B. When the second rotary drive device **24** rotates the frame **22** about axis C, the strand S may be twisted about its own axis as it is unwound from the input spool **18**.

In operation, rotary drive device **24** may rotate the frame **22** about axis C while strand S is pulled by take-up mechanism **20**. Strand S may unwind from the input spool **18** in a helically twisted state and may be received and supported on an outer surface **15** of the support member **14** as it travels toward the take-up mechanism **20**. In the embodiment shown in FIG. **1**, support member **14** may be a sheave which is rotatable about an axis extending perpendicular to the axis A. The outer surface **15** of the support member **14** may include a channel or groove (not shown) for receiving the strand S.

The retainer forming member **11** and the support member **14** may be moveable relative to one another in at least two directions. For example, retainer forming member **11** may be moveable in one or both of directions F**1** and F**2** as shown in FIG. **1** to position the passing strand S such that retainers can be continuously or intermittently formed thereon by the blade **13** of the retainer forming member **11** during rotation of the retainer forming member **11** about axis A. Alternatively, support member **14** may be moveable in one or both of directions F**1'** and F**2'** as shown in FIG. **1** to position the passing strand S such that retainers can be continuously or intermittently formed thereon by the blade **13** of the retainer forming member **11** during rotation of the retainer forming member **11** about axis A. Thus, although the support member **14** is shown in FIG. **1** as having an alternative position relative to the retainer forming member **11** (denoted by a dotted outline), either one of the retainer forming member **11** and support member **12** may move relative to the other to position the strand S as necessary for cutting. As will be discussed in greater detail below with reference to FIGS. **2**A, **2**B, **3**A, **3**B, **4**A, and **4**B, such relative movement may provide the apparatus **10** with the ability to engage and disengage the blade **13** from contact with the strand S as well as vary the depth and angle of cut and the retainer direction (i.e., left-hand retainer versus right-hand retainer). Additionally, any relative motion changing the depth of the cut can be used, such as, for example, moving the retainer forming member **12** or support member **15** along an axis extending into or out of the page according to the view shown in FIG. **1**. The angle of cut may be changed, for example, by moving the retainer forming member **12** along axis A and re-adjusting the depth of cut. In general, the members **12** and **15** can be moved in many degrees of freedom relative to one another to achieve different cutting properties.

As can be seen in FIG. **1**, the take-up mechanism **20** may be positioned downstream of the retainer forming member **11** and the support member **14** based on the direction of flow of the strand S. Although shown generically in FIG. **1**, the take-up mechanism **20** may be, for example, an output spool arranged to wind the strand S thereon or it may be another processing device such as, for example, a mechanism which gathers the strand S and severs the continuous strand S at predetermined length intervals. The apparatus **10** can also be coupled to another unit down the production line such as, for example, a machine configured to crimp needles to the strand S.

FIGS. **2**A and **2**B depict schematic bottom and side cross-sectional views of the retainer forming member **11**. The main body **12** of the retainer forming member **11** is depicted as a circular ring having an inner annular surface **12***a* and an outer annular surface **12***b*. The blade **13** may be attached to the main body **12**. In FIGS. **2**A and **2**B, the blade **13** is shown as being attached via fasteners **19** (e.g., bolts or screws) but one of skill in the art will recognize that other suitable attachment measures may be used such as, for example, but not limited to, welding, adhesive, snap fit, friction fit, and the like. Alternatively, the blade **13** could be integrally formed on the main body **12**. The blade **13** may have a cutting edge **13***a* directed substantially radially inward such that, when the retainer forming member **11** is rotating, the cutting edge **13***a* of the blade **13** defines a retainer forming zone Z. Although the blade **13** is shown as having a flat cutting edge **13***a*, it will be apparent that cutting edge **13***a* could take on a variety of other configurations (not shown) including, for example, but not limited to, straight, curved, stepped, slanted, etc. Furthermore, the cutting edge **13***a* of blade **13** can extend linearly across a portion of the area defined by the inner surface **12***a* as shown in FIGS. **2**A and **2**B but may also be formed as a continuous or intermittent annular cutting edge (not shown) which extends inward from the inner surface **12***a*. A continuous helical retainer about the outer surface of the strand S may be cut by a rotating blade making continuous contact with the suture so long as the pitch is very tight, e.g., thread-like, or by keeping the blade stationary and rotating the strand S at high speed, similar to thread cutting on a lathe. Additionally, the angle of the blade **13** with respect to the plane of rotation of the retainer forming member **11** may vary to provide different types of cutting action and, as a result, differently shaped retainers as may be desired.

The blade **13** is shown in FIG. **2**B as being tilted relative to the plane or rotation. This configuration may provide desired lifting action as the blade **13** contacts and slices through the strand S as each retainer is cut. In effect, the cutting point is lifted or changed as blade **13** rotates (by as much as, for example, 1-2 mm). This lifting action can be important for materials such as, for example, lower modulus suture material, in which a formed retainer may tend to close back against the body of the strand S after cutting.

FIG. **3**A is a cross-sectional side view of the retainer forming member **11** with the support member **14** shown in a first operational cutting position within the retainer forming zone Z to form right-handed retainers RHB on the helically twisted passing continuous strand S with blade **13** as the retainer forming member **12** rotates about axis A. FIG. **3**B is a detailed view of the retainer forming member **11** and the support member **14** according to the embodiment shown in FIG. **3**A.

In order to achieve good cutting action the blade **13** may be positioned to simultaneously slide across the strand S as it penetrates the strand S during rotation to define a smooth slicing motion. If this is not done, the cutting action can be poor and the blade can dull rapidly, as cutting is done by a single point on the blade. In order to achieve high speed, the retainer forming member **12** may rotate in unidirectional rotary motion about axis A. Any reciprocation motion (linear or rotational) may induce vibration, larger forces, and, as a result, operational speed may be limited.

FIG. **4**A is a cross-sectional side view of the retainer forming member **11** with the support member **14** shown in a second operational cutting position within the retainer forming zone Z to form left-handed retainers LHB on the helically twisted passing continuous strand S with blade **13** as the retainer forming member **12** rotates about axis A. FIG. **4**B is a detailed view of the retainer forming member **11** and the support member **14** according to the embodiment shown in FIG. **4**A.

FIG. **5** is a schematic view of an apparatus **100** for forming retainers in a continuous strand S according to another embodiment of the invention. The apparatus **100** is the same as the embodiment shown in FIG. **1** except that the apparatus **100** may additionally include a strand tension maintenance mechanism **30** positioned between the feed mechanism **16** and the cutting and support members **11**, **14** along the path of travel of the continuous strand S. As shown in FIG. **5**, a plurality of intermediate sheaves or pulleys **32**, **34**, **36** may be disposed at offset positions along the path of travel of the continuous strand S to regulate tension in the strand S as it travels to the support member **14**. A constant tension device **38** which may be, for example, a spring, may couple one of the intermediate sheaves, e.g., sheave **34**, to a stationary frame or body to provide constant tension in the strand S. Tensioning devices such as, for example, springs, magnetic particle brakes, electric motors, mechanical friction brakes, eddy current brakes, hysteresis brakes, and the like, are well known in the art and will not be described further herein.

In the previously described embodiments of FIGS. **1-5**, the continuous strand S can be helically twisted about its own axis by rotary drive device **24** such that when the blade **13** of the retainer forming member **11** cuts retainers into the passing continuous strand S along a line extending parallel to the axis of the strand S, the strand S can then be untwisted so that the retainers formed thereon may extend along the length of the strand S in a helical configuration.

FIG. **6** is a schematic view of an apparatus **200** for forming retainers in a continuous strand S according to yet another embodiment of the invention wherein the strand S is not helically twisted about its own axis but, rather, is uniformly rotated about its own axis along its entire exposed length. In this regard, any deleterious effects on the strand S due to twisting such as, for example, cracking, splitting, strain hardening, delamination, and the like, may be alleviated.

In the embodiment depicted in FIG. **6**, a feed mechanism **216** may be provided having an input spool **218** freely rotatable about axis B and supported by frame **222**. Frame **222** may be arranged to be rotatably driven about axis C by rotary drive device **224** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor), wherein axis C is shown as being perpendicular to axis B. Likewise, a take-up mechanism **216'** may be provided having an output spool **218'** freely rotatable about axis B' and supported by frame **222'**. Frame **222'** may be arranged to be rotatably driven about axis C' by rotary drive device **224'** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor), wherein axis C' is shown as being perpendicular to axis B'. The feed mechanism **216** and take-up mechanism **216'** may be configured to rotate concurrently in a predetermined direction as the strand S is pulled from the input spool **218** by the output spool **218'** so that the strand S uniformly rotates about its own axis along its length to avoid twisting.

Still referring to FIG. **6**, the apparatus **200** may include a retainer forming member **211** arranged to be rotatably driven about an axis A by rotary drive device **217** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor). The retainer forming member **211** may include a main body **212** and a blade **213** attached to or integrally formed on the main body **212** having a cutting edge **213***a* directed substantially inward toward axis A. A support member **214** may be provided adjacent to the retainer forming member **211** and within a retainer forming zone Z. As described above with regard to the embodiment depicted in FIGS. **1-4**, the retainer forming member **211** and support member **214** shown in FIG. **6** may be moveable relative to one another. The strand S may be received and supported on an outer surface of the support member **214** as the strand S passes from input spool **218** to output spool **218'**. The outer surface of support member **214** in this embodiment may have a relatively small surface area to receive and support the strand S in the retainer forming zone Z such that, when the blade **213** cuts right-handed retainers RHB on the passing strand S, the retainers RHB do not contact the outer surface of the support member **214** as the strand S rotates about its own axis. FIG. **7** depicts a more detailed illustrative perspective view of the apparatus **200** in FIG. **6** showing the strand S as it passes over the support member **214** while right-handed retainers RHB are cut by the blade **213**. In the detailed view shown in FIG. **7**, the retainers RHB may not contact the outer surface of the support member **214** as the passing strand S rotates about its own axis.

FIG. **8** is a schematic view of an apparatus **300** for forming retainers in a continuous strand S according to another embodiment of the invention. The apparatus **300** is the same as the embodiment shown in FIG. **6** except that the apparatus **300** may additionally include a strand tension maintenance mechanism **330** positioned between the feed mechanism **216** and the cutting and support members **211**, **214** along the path of travel of the continuous strand S. As shown in FIG. **8**, a plurality of intermediate sheaves or pulleys **332**, **334**, **336** may be disposed at offset positions along the path of travel of the continuous strand S to regulate tension in the strand S as it travels to the support member **214**. A constant tension device **338** which may be, for example, a spring, may couple one of the intermediate sheaves, e.g., sheave **334**, to a stationary frame or body to provide constant tension in the strand S. Support element **214** is also shown in a position relative to the retainer forming member **211** such that left-handed retainers LHB may be cut on the passing continuous strand S.

FIG. **9** is a schematic view of an apparatus **400** for forming retainers in a continuous strand S according to still another embodiment of the invention. A feed mechanism **416** may be provided which may include an input spool **418** about which a continuous strand S is wound. Input spool **418** may be arranged to freely rotate about an axis B as strand S is pulled by a take-up mechanism **420**. In the embodiment depicted in FIG. **9**, the strand S may not be rotated or twisted about its own axis. Instead, a plurality of support members **414**, **414'** and retainer forming members **411**, **411'** may be disposed between the feed mechanism **416** and the take-up mechanism **420** along a path of travel of the strand S and at differing circumferential positions about the strand S to cut retainers along and around the exterior of strand S. For example, as shown in FIG. **9**, as strand S is unwound from input spool **418** it may be received and supported on an outer surface **415** of a support element **414** which may be disposed adjacent to a retainer forming member **411**. The retainer forming member **411** may include a main body **412** and a blade **413** having a cutting edge directed substantially inward toward an axis A about which the retainer forming member **411** is rotatably driven by rotary drive device **417** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor). The support member **414** and retainer forming member **411** may be moveable relative to one another. In the embodiment shown in FIG. **9**, the support member **414** and retainer forming member **411** may be positioned such that the blade **413** can cut left-handed retainers LHB axially along the exterior surface of the strand S.

After passing over support member **414** and being cut by retainer forming member **211**, the strand S may travel toward and may be received and supported on the outer surface **415'** of another support member **414'** which may be disposed adjacent to another retainer forming member **411'**. The additional retainer forming member **411'** may include a main body **412'** and a blade **413'** having a cutting edge directed substantially inward toward an axis A' about which the retainer forming member **411'** may be rotatably driven by rotary drive device **417'** (e.g., an electric, pneumatic, hydraulic, or magnetic servo motor). The support member **414'** and retainer forming member **411'** may be moveable relative to one another. In the embodiment shown in FIG. **9**, the support member **414'** and retainer forming member **411'** are positioned such that the blade **413'** can cut another set of left-handed retainers LHB' axially along the exterior surface of the strand S at a different circumferential position about the strand S than the line of retainers LHB cut by the retainer forming member **411**. In this way, two circumferentially spaced lines of retainers may be formed along the length of strand S.

Although FIG. **9** only shows two retainer forming members **411**, **411'** and two support members **414**, **414'** disposed between the feed mechanism **416** and the take-up mechanism **420** along a path of travel of the strand S at differing circumferential positions about the strand S, one of skill in the art will recognize that any number of corresponding retainer forming member and support member combinations may be disposed along the path of travel of the strand S at additional differing circumferential positions about the strand S to cut retainers along and around the exterior of strand S. Finally, in FIG. **9**, take-up mechanism **420** may be positioned downstream of the retainer forming members **411**, **411'** and the support members **414**, **414'** based on the direction of flow of the strand S. Although shown generically in FIG. **9**, the take-up mechanism **420** may be, for example, an output spool arranged to wind the strand S thereon or it may be another processing device such as, for example, a mechanism which gathers the strand S and severs the continuous strand S at predetermined length intervals.

FIG. **10** is a schematic view of an apparatus **500** for forming retainers in a continuous strand S according to another embodiment of the invention. The apparatus **500** is the same as the embodiment shown in FIG. **9** except that the apparatus **500** may additionally include a strand tension maintenance mechanism **430** positioned between the feed mechanism **416** and the first cutting and support members **411**, **414** along the path of travel of the continuous strand S. As shown in FIG. **10**, a plurality of intermediate sheaves or pulleys **432**, **434** may be disposed at offset positions along the path of travel of the continuous strand S to regulate tension in the strand S as it travels to the first support member **414**. A constant tension device **436** which may be, for example, a spring, may couple one of the intermediate sheaves, e.g., sheave **434**, to a stationary frame or body to provide constant tension in the strand S. Support elements **414**, **414'** are also shown in a position relative to the retainer forming members **411**, **411'** such that left-handed retainers LHB, LHB' may be cut on the passing continuous strand S.

In each of the foregoing embodiments shown in FIGS. **1-10**, a plurality of process variables are presented which, when modified singularly or in combination with other variables, can produce a strand S having theoretically countless retainer configurations thereon. These process variables include, for example, the rotational speed of the retainer forming member; the linear speed of the strand S through the apparatus; the rate or amount of twist/rotation of the strand S about its own axis; the horizontal and vertical position of the support member relative to the retainer forming member which may determine the cut depth of the formed retainer, angle of the retainer cut, and the forming of left-hand versus right-hand retainers. The foregoing variables may be selected alone or in combination depending on the gauge and composition of the strand S and/or the intended use of the sutures being produced and desired retainer configuration. Other variables may include, for example, the upwards tilt of the blade, the curvature of the cutting edge, the way the cutting edge is ground (one or both sides), the material of the blade (e.g., steel, carbide, ceramic, diamond), the coating of the blade (e.g., ceramic, diamond), and the lubrication applied during the cutting process (e.g., water, soap, gel, other conventional lubricants). Depending on the material of strand S, it may be desired to cut retainers at a temperature higher or lower than room temperature, in order to change the cutting characteristics.

In another embodiment of the apparatus (not shown), the retainer forming member may have a blade with a cutting edge directed substantially outward away from the axis about which the retainer forming member rotates. The support member may be positioned adjacent to the retainer forming member and the support and/or retainer forming members may be moveable relative to one another. The blade may be unidirectionally rotated about the axis to cut retainers in a continuous strand of suture material passing over the support member.

FIGS. **11**A-D and **12**A-B are schematic depictions of the various states of the continuous strand S when twisted about its own axis, cut to form retainers, and then untwisted to reveal a plurality of retainers formed helically along the length of the strand S. FIG. **11**A shows the continuous strand S prior to being twisted, rotated, or cut. In FIG. **11**A the strand S is shown unmodified, with an imaginary line **601** shown to depict a line along the exterior of the strand S and extending parallel to the longitudinal axis of the strand S. FIG. **11**B shows the continuous strand S during or after being twisted about its own axis but prior to being cut. Line **601** is shown extending helically about the exterior of the strand S. FIG. **11**C shows the strand S after being twisted and cut to have retainers **602** facing in a first direction (i.e., left-handed retainers). FIG. **11**D shows the strand S of FIG. **11**C after being untwisted from a twisted state. The retainers **602** may be positioned along the length of the strand S in a helical configuration to define, for example, a one-way self-retaining suture.

FIG. **12**A shows the strand S after being twisted and cut to have retainers **702** facing in a second direction (i.e., right-handed retainers). Line **601** is shown extending helically about the exterior of the twisted strand S. FIG. **12**B shows the strand S of FIG. **12**A after being untwisted from a twisted state. The retainers **702** may be positioned along the length of the strand S in a helical configuration to define, for example, a one-way self-retaining suture. The apparatus **10** may also be used to produce two-way self-retaining sutures (not shown).

In any of the above described embodiments, it will be appreciated that by moving the retainer forming members and support members relative to one another during operation, altering the speed of travel of the strand S, altering the twist or rotation of the strand S about its own axis, altering the rotational speed of the retainer forming member, adjusting the angle of the blade and/or the relative orientations of the cutting and support members, etc., retainers can be formed in a uniform, semi-random or complex patterns (i.e. having a combination of periods) on the exterior of the strand S.

The strand S in any of the foregoing embodiments may comprise a suture material. More particularly, the strand S may be any absorbable and/or non-absorbable material suitable to produce sutures when cut such as, for example, as described in International PCT Application Publication No. WO 2007/089864, the entirety of which is hereby incorporated by reference. Absorbable sutures are generally made of materials that will break down harmlessly in the body over time without intervention and can, therefore, be utilized internally. One exemplary natural absorbable suture material that may form the suture includes catgut (typically specially prepared beef and sheep intestine). Catgut may be untreated (plain gut), tanned with chromium salts to increase their persistence in the body (chromic gut), or heat-treated to give more rapid absorption (fast gut). The suture may also be a synthetic absorbable suture formed from synthetic polymer fibers, which may be braided or monofilament, including, for example, various blends of polyglycolic acid (PGA), lactic acid, polydioxanone (PDS), or caprolactone.

Alternatively, the suture may be a non-absorbable suture made of materials which are not metabolized by the body and must be manually removed. Non-absorbable sutures are generally used either on skin wound closure, where the sutures can be readily removed after a few weeks, or in some internal tissues in which absorbable sutures are not adequate. The suture may be formed from a natural non-absorbable suture material such as, for example, silk, which may undergo a special manufacturing process to make it adequate for use in surgery. Other suitable nonabsorbable materials for the suture may include artificial fibers such as, for example, polypropylene, polyester or nylon, or blends thereof. These materials may or may not have coatings to enhance their performance characteristics. Finally, the suture may be formed of stainless steel wire for use in, for example, orthopedic surgery or for sternal closure in cardiac surgery. Other materials may include, for example, but not limited to, polyethylene, polycarbonate, polyimide, polyamide, polyglactin, polyepsilon-caprolactone, polyortho ester, polyethyler, and/or blends thereof, and/or copolymers.

While various exemplary embodiments of the present invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should instead be defined only in accordance with the following claims and their equivalents.

The invention claimed is:

1. An apparatus for forming retainers on a continuous strand, comprising:

a retainer forming member configured to rotate about a first axis and comprising a cutter, the cutter comprising a cutting edge, wherein the cutting edge of the cutter is directed substantially inward toward the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis; and

a support member arranged adjacent to the retainer forming member and configured to receive and support the continuous strand in the retainer forming zone, wherein when the retainer forming member rotates about the first axis the strand is intermittently or continuously cut by the cutting edge of the cutter.

2. The apparatus of claim **1**, wherein said support member has a support member axis, wherein said support member axis is substantially perpendicular to said first axis.

3. The apparatus of claim **1**, wherein when the retainer forming member rotates about the first axis the strand is cut to form a plurality of retainers.

4. A method for forming retainers on a continuous strand with an apparatus, the apparatus comprising a retainer forming member configured to rotate about a first axis and comprising a cutter, wherein a cutting edge of the cutter is directed substantially inward toward the first axis to define a retainer forming zone when the retainer forming member rotates about the first axis, and a support member arranged adjacent to the retainer forming member and configured to receive and support the continuous strand in the retainer forming zone, the method comprising:

rotating the retainer forming member of the apparatus about the first axis;

moving the continuous strand on the support member within the retainer forming zone; and

intermittently or continuously cutting the strand with the cutting edge of the cutter as the retainer forming member rotates to form retainers on the strand.

5. The method of claim **4**, wherein said support member has a support member axis, wherein said support member axis is substantially perpendicular to said first axis.

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